Table 1

Stage	Number Tested	Acceptance Criteria
S_1	6	Each unit is within the range Q ± 30%.
S_2	6	Average of 12 units (S_1 + S_2) is within the range between Q − 30% and Q + 35%, and no unit is outside the range Q ± 40%.
S_3	12	Average of 24 units (S_1 + S_2 + S_3) is within the range between Q − 30% and Q + 35%, and NMT 2 units are outside the range Q ± 40%.

Test 2: If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 2*.

Standard stock solution and **Standard solutions:** Prepare as directed in *Test 1*.

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Times: 1, 2, 4, and 6 h

Sample stock solution: Transfer 4.0 mL of the solution under test into a 50-mL volumetric flask, dilute with water to volume, and filter.

Sample solution: Transfer 4.0 mL of the *Sample stock solution* to a 100-mL volumetric flask. Add 2.0 mL of sodium chloride solution (200 mg/mL) and 1.0 mL of hydrochloric acid, and dilute with water to volume.

Blank solution: To a 100-mL volumetric flask, add 2.0 mL of sodium chloride solution (200 mg/mL) and 1.0 mL of hydrochloric acid, and dilute with water to volume.

Instrumental conditions: Proceed as directed in *Test 1*, except do not use the *Blank*.

System suitability

Samples: *Standard solutions*

Suitability requirements

Linearity: Correlation coefficient NLT 0.99

Relative standard deviation: NMT 5.0% from 5 replicate analyses of the 1.5-µg/mL *Standard solution*

Analysis

Samples: 1.5-µg/mL *Standard solution*, *Sample solution*, and *Blank solution*

Calculate the percentage of the labeled amount of potassium chloride (KCl) dissolved:

$$\text{Result}_i = [(A_U/A_S) \times C_S \times D \times (V/L)] \times (M_r/A_r) \times 100$$

A_U = absorbance of potassium in the *Sample solution*

A_S = absorbance of potassium in the *Standard solution*

C_S = concentration of potassium in the *Standard solution* (µg/mL)

D = dilution factor of the *Sample solution*

V = volume of *Medium*, 900 mL

L = labeled amount of potassium chloride (µg/Capsule)

M_r = molecular weight of potassium chloride, 74.55

A_r = atomic weight of potassium, 39.10

Tolerances: See *Table 2*.

Table 2

Time Point (*i*)	Time (h)	Amount Dissolved (%) 750 mg/Capsule
1	1	25–45
2	2	45–65
3	4	70–90
4	6	NLT 85

The percentages of the labeled amount of potassium chloride (KCl), dissolved at the times specified, conform to *Dissolution* ⟨711⟩, *Acceptance Table 2*.

▲**Test 4:** If the product complies with this procedure, the labeling indicates that it meets USP *Dissolution Test 4*.

[NOTE—Use water with a conductivity of NMT 1 µS/cm to prepare solutions, except *Medium*.]

Medium: Water; 900 mL

Apparatus 1: 100 rpm

Times: 1, 2, 4, and 8 h

Solution A: 100 mM methanesulfonic acid prepared as follows. Transfer 6.5 mL of methanesulfonic acid to a 1000-mL volumetric flask and dilute with water to volume.

Mobile phase: *Solution A* and water (20:80)

Standard stock solution: 600 µg/mL of USP Potassium Chloride RS in water

Standard solution A: 3 µg/mL of USP Potassium Chloride RS in water from *Standard stock solution*

Standard solution B: 12 µg/mL of USP Potassium Chloride RS in water from *Standard stock solution*

Standard solution C: 30 µg/mL of USP Potassium Chloride RS in water from *Standard stock solution*

Standard solution D: 48 µg/mL of USP Potassium Chloride RS in water from *Standard stock solution*

Standard solution E: 60 µg/mL of USP Potassium Chloride RS in water from *Standard stock solution*

Standard solution F: 72 µg/mL of USP Potassium Chloride RS in water from *Standard stock solution*

Standard solution G: 90 µg/mL of USP Potassium Chloride RS in water from *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size at the times specified, discarding the first few milliliters of the filtrate. Replace the portion removed with same volume of *Medium*. Dilute the filtrate with water, if necessary, to obtain a solution with a concentration similar to that of *Standard solution E*.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: Conductivity with suppression

Columns

Guard: 4-mm × 5-cm; 8.5-µm packing L106

Analytical: 4-mm × 25-cm; 8.5-µm packing L106

Suppressor: 4-mm cation or a suitable suppressor

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 50 µL

Run time: NLT 2.5 times the retention time of potassium

System suitability

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, *Standard solution E*, *Standard solution F*, and *Standard solution G*

Suitability requirements

Tailing factor: NMT 2.0, *Standard solution E*

Relative standard deviation: NMT 2.0%, *Standard solution E*

Correlation coefficient: NLT 0.999, from the linear regression in the *Analysis*

Y-intercept: ±2% of *Standard solution E* response, from the calibration curve in the *Analysis*

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, *Standard solution E*, *Standard solution F*, *Standard solution G*, and *Sample solution*

Determine the responses for *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, *Standard solution E*, *Standard solution F*, and *Standard solution G*. Construct a linear calibration curve by plotting response values of *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, *Standard solution E*, *Standard solution F*, and *Standard solution G* versus their corresponding concentrations in mg/mL.

From the linear calibration curve, determine the C*orrelation coefficient* and *Y-intercept*.

Calculate the concentration (C_i) of potassium chloride (KCl) in the sample withdrawn from the vessel at time point *i*:

$$\text{Result} = (r_U/r_S) \times C_S \times D$$

r_U = peak response of potassium from the *Sample solution* at time point *i*

r_S = peak response of potassium from *Standard solution E*

C_S = concentration of USP Potassium Chloride RS in *Standard solution E* (mg/mL)

D = dilution factor of the *Sample solution*, if needed

Calculate the percentage of the labeled amount of potassium chloride (KCl) dissolved at each time point (*i*):

$$\text{Result}_1 = C_1 \times V \times (1/L) \times 100$$

$$\text{Result}_2 = [(C_2 \times V) + (C_1 \times V_S)] \times (1/L) \times 100$$

$$\text{Result}_3 = \{(C_3 \times V) + [(C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

$$\text{Result}_4 = \{(C_4 \times V) + [(C_3 + C_2 + C_1) \times V_S]\} \times (1/L) \times 100$$

C_i = concentration of potassium chloride in the portion of sample withdrawn at time point *i* (mg/mL)

V = volume of *Medium*, 900 mL

L = label claim (mg/capsule)

V_S = volume of the *Sample solution* withdrawn at each time point (mL)

Tolerances: See *Table 3*.

Table 3

Time Point (*i*)	Time (h)	Amount Dissolved (%)
1	1	NMT 20
2	2	25–45
3	4	55–80
4	8	NLT 80

The percentage of the labeled amount of potassium chloride (KCl) dissolved at the times specified conforms to *Dissolution* ⟨711⟩, *Acceptance Table 2*. ▲ (RB 1-Jan-2021)

- **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and store at a temperature not exceeding 30°.
- **Labeling:** When more than one *Dissolution* test is given, the labeling states the *Dissolution* test used only if *Test 1* is not used.

Add the following:

▲● **USP Reference Standards** ⟨11⟩

USP Potassium Chloride RS ▲ (RB 1-Jan-2021)

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